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Attorneys for Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc.

## [Counsel continued below]

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

MUTUAL PHARMACEUTICAL COMPANY, INC., et al.,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., et al.,

Defendants.

Civil Action No. 09-5421(GEB)(TJB)

DECLARATION OF NISHAN KOTTAHACHCHI IN SUPPORT OF PLAINTIFFS' OPPOSITION TO THE MOTION FOR SUMMARY JUDGMENT FILED BY DEFENDANT WEST-WARD PHARMACEUTICAL CORP.

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## I, Nishan Kottahachchi, declare and state as follows:

- 1. I am an attorney licensed to practice law in the State of California and the District of Columbia, and am admitted *pro hac vice* in this matter before this Court. I am an associate in the law firm of Cooley LLP, attorneys of record in this matter for Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding, Inc. (collectively "Plaintiffs"). I have personal knowledge of the facts set forth in this Declaration, and if called upon to testify I could and would testify competently thereto.
- 2. Attached hereto as Exhibit A is a true and correct copy of a page from the United States Food and Drug Administration ("FDA") website titled *Guidance for FDA staff and Industry: Marketed Unapproved Drugs—Compliance Policy Guide*, publicly available at <a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070290.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070290.pdf</a>, and last viewed on August 20, 2010.
- 3. Attached hereto as Exhibit B is a true and correct copy of the FDA warning letter to Sunrise Pharmaceutical, Inc., publicly available on the FDA's website at

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm197966.htm and last viewed on August 20, 2010.

- 4. Attached hereto as Exhibit C is a true and correct copy of the FDA's warning letter to Concord Laboratories, Inc., publicly available on the FDA's website at
- http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075988. htm and last viewed on August 20, 2010.
- 5. Attached hereto as Exhibit D is a true and correct copy of the FDA's warning letter to Defendant Vision Pharma LLC, publicly available on the FDA's website at

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm212242.htm and last viewed on August 20, 2010.

- 6. Attached hereto as Exhibit E is a true and correct copy of a page from the FDA website titled *National Drug Code Directory*, publicly available at <a href="http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm">http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm</a>, and last viewed on August 20, 2010.
- 7. Attached hereto as Exhibit F is a true and correct copy of a page from the FDA's website titled *FDA Acts to Improve Drug Safety and Quality*, publicly available at <a href="http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm1086">http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm1086</a> 65.htm, and last viewed on August 20, 2010.
- 8. Attached hereto as Exhibit G is a true and correct copy of a page from the FDA's website titled *Questions and Answers About FDA's Enforcement Action Against Unapproved Injectable Colchicine Products*, publicly available at <a href="http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Enforceme">http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Enforceme</a> <a href="http://www.fda.gov/Drugs/guidanceComplianceRegulatoryInformation/EnforcementActionsonUnapprovedDrugs/ucm119642">http://www.fda.gov/Drugs/guidanceComplianceRegulatoryInformation/EnforcementActionsonUnapprovedDrugs/ucm119642</a>.

  <a href="http://www.fda.gov/Drugs/guidanceComplianceRegulatoryInformation/EnforcementActionsonUnapprovedDrugs/ucm119642">http://www.fda.gov/Drugs/guidanceComplianceRegulatoryInformation/EnforcementActionsonUnapprovedDrugs/ucm119642</a>.
- 9. Attached hereto as Exhibit H is a true and correct copy of Defendant West-Ward Pharmaceutical Corp.'s Responses and Objections to Plaintiff Mutual Pharmaceutical Company, Inc.'s First Set of Requests for Admission.
- 10. Attached hereto as Exhibit I is a true and correct copy of the Objections and Responses of Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc. to Defendant West-Ward Pharmaceutical Corp.'s First Set of Requests for Admission.
- 11. Attached hereto as Exhibit J is a true and correct copy of Plaintiff Mutual Pharmaceutical Company, Inc.'s Objections and Responses to Defendant West-Ward Pharmaceutical Corp.'s First Set of Interrogatories.

12. Attached hereto as Exhibit K is a true and correct copy of Second Supplemental Responses of Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc. to Defendant West-Ward Pharmaceutical Corp.'s First Set of Interrogatories.



16. Attached hereto as Exhibit O is a true and correct copy of a page from the FDA website titled *Single-Ingredient Oral Colchicine Video*, publicly available at <a href="http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211975.htm">http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211975.htm</a>, and last viewed on August 23, 2010.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed at Washington, District of Columbia on August 23, 2010.